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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,304	07/03/2003	Jacob Mathiesen	065334-0110	3190

7590 09/05/2006

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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,304	Applicant(s) MATHIESEN ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/07/04; 01/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Election/Restrictions

Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 19, 2006.

Claim Rejections - 35 USC § 102

Claims 14, 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Townsend, U.S. 4,220,669. Although Townsend discloses a method of preparing meat, it meets the limitations of the claimed invention. The fluid is injected during insertion of the needle, dependent upon the speed of the needle. Regarding claim 16, note that fluid flow is commenced using the meat thickness sensor so that fluid injection is commenced when the needle penetrates the meat, which anticipates the claimed "injection being commenced when the needle reaches a first desired depth in the body tissue." Fluid flow is stopped before the needle exits the meat, which anticipates the claimed "stopped when the needle reaches a second desired depth in the body tissue."

Claims 14, 15, 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schmitz, U.S. 5,620,421. See the Abstract, disclosing that injection of

Art Unit: 1615

medicament occurs during needle insertion. Note also column 1, lines 25-40, discussing the known concept of a "tracked injection."

Claims 14 and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hofmann et al., US 6,181,964. The concept of "fanning" in combination with electroporation is disclosed. See column 13, line 44 to column 14, line 3.

Claims 14, 19 and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hofmann et al., U.S. 6,418,341. See sheet 6 where the needles are withdrawn and replaced by electrodes. The concept of "fanning" is described in column 10, lines 31-55.

Claim 21 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dalamagas et al., US 5,271,413. See especially the abstract, disclosing measuring the impedance.

Claim Rejections - 35 USC § 103

Claims 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai, U.S. 2003/0073908.

Desai discloses the method of inserting a needle to a specific depth using various technologies including ultrasound. See sheet 1. In paragraph [0048], last lines, Desai states that once treatment is administered to a site, the needle can be withdrawn from the patient, or can be "advanced into the tissue, and a sufficient volume of fluid is injected." Accordingly, Desai discloses the concept of repeated injections while advancing the needle, although Desai does not appear to specifically disclose the

concept of moving the needle forward and injecting at the same time (tracking injection technique). However, the examiner takes the position that this would be obvious to one of ordinary skill in the art to inject and advance the needle as this concept is known and in view that this would distribute the medicament evenly along the tissue.

Claims 14, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalamagas '413. Regarding claims 14 and 17, Dalamagas exemplifies that using impedance to determine needle depth is well known. Dalamagas does not disclose the technique of injecting the medicament while inserting the needle into a patient, otherwise known as a "tracked injection." However, it would be obvious to one of ordinary skill in the art to use the Dalamagas device in a tracked injection technique if it were desired to minimize pain in the patient. Regarding claim 22, Dalamagas discloses the reference electrode as being attached to the surface of the skin. Claim 22 requires that the reference electrode be another needle. It would be obvious to one of ordinary skill in the art at the time the invention was made to use any type of reference electrode, including an additional needle, dependent upon the use of the reference electrode.

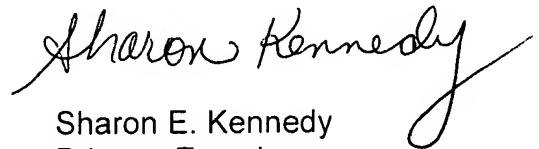
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Sharon Kennedy", with a stylized flourish at the end.

Sharon E. Kennedy
Primary Examiner
Art Unit 1615